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EXAMINER	
TOTH, KAREN E	

ART UNIT	PAPER NUMBER
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/797,583	LANGSTON, PHIL	
	Examiner	Art Unit	
	Karen E. Toth	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-23* is/are pending in the application.

4a) Of the above claim(s) *13-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

2. Claims 1, 2, 6, 8-11, and 23 rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (US Patent 5480380) in view of Ladika (US Patent 4747840) and Bodicky (US Patent 4961731).

Regarding claim 1, Martin discloses a catheter comprising a manifold portion (element 24) comprising a first connector and a second connector (elements 36 and 38 – see figure 1); a coaxial dual lumen portion (element 22) comprising an inner lumen wall in communication with one connector and an outer lumen wall in communication with the other connector (see figure 8), where the distal end of the outer lumen wall contains a plurality of perforations (elements 48); and a single lumen portion with a generally straight portion (figure 1) in fluid communication with the inner lumen portion (see figure 6), where the lumen wall contains at least one side hole (element 50). Martin does not disclose the single lumen portion comprising a pigtail portion distal to a straight portion of the single lumen, or the inner lumen wall comprising braided extrusion reinforcement to accommodate high-pressure injections.

Ladika teaches a catheter comprising a single lumen portion with a straight section (element 26) and a pigtail portion (element 18) distal to the straight portion (see

figure 1), in order to prevent the catheter from puncturing the patient's tissue (column 1, lines 60-66).

Bodicky teaches a cardiac catheter made of braided tubing (column 3, lines 8-20), in order to reinforce the device for high-pressure injections.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Martin with a distal pigtail section, as taught by Ladika, in order to prevent the catheter from puncturing the patient's tissue, and formed the inner lumen with braided extrusion reinforcement tubing, as taught by Bodicky, in order to reinforce the device for high-pressure injections.

Regarding Claim 2, Martin further discloses the presence of a tapering portion (element 66) between the dual and single lumen sections of the device (see Figure 6).

Regarding Claim 6, Martin in view of Ladika and Bodicky discloses all the elements of the current invention, as applied to Claim 1 above, except for the inner lumen side holes being distributed in a spiral pattern over about 2 centimeters. Ladika further teaches that the single lumen portion comprises side holes that are distributed in a spiral array, in order to evenly distribute fluids. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the catheter of Martin in view of Ladika and Bodicky, and distributed the inner lumen side holes in a spiral array, as taught by Ladika, in order to evenly distribute fluids.

Regarding Claim 8, Martin in view of Ladika and Bodickydiscloses all the elements of the current invention, as applied to Claim 1 above, except for the single lumen portion further comprising a second straight portion joined to the first straight

portion by a bend. Ladika further teaches that the single lumen portion of the catheter comprises a second straight portion (element 28) joined to the first straight portion (element 26) by a bend (element 22) (see Figure 1), in order to allow easier maneuvering inside a patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the catheter of Martin in view of Ladika and Bodicky, and added the second straight portion to the single lumen section, as taught by Ladika, in order to allow easier maneuvering inside a patient.

Regarding Claim 9, Martin in view of Ladika and Bodicky discloses all the elements of the current invention, as applied to Claim 8 above, except for the angle between the first and second straight portions of the inner lumen being between about 130 and about 160 degrees. Ladika further teaches that the bend (element 22) between straight portions (elements 28 and 30) is between about 130 and about 160 degrees (column 5, lines 4-7), in order to properly maneuver within a patient's heart. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the catheter of Martin in view of Ladika and Bodicky, and formed the bend between straight portions of the inner lumen to be between about 130 and about 160 degrees, as taught by Ladika, in order to properly maneuver within a patient's heart.

Regarding Claim 10, Martin in view of Ladika and Bodicky discloses all the elements of the current invention, as applied to Claim 9 above, except for the angle of the bend being about 145 degrees. Ladika further teaches that the angle of the bend is about 145 degrees (column 5, lines 4-7), in order to properly maneuver within a patient's heart. It would have been obvious to one of ordinary skill in the art at the time

the invention was made to have made the catheter of Martin in view of Ladika and Bodicky, and formed the bend between straight portions of the inner lumen to be about 145 degrees, as taught by Ladika, in order to properly maneuver within a patient's heart.

Regarding claim 11, MPEP section 2113 states:

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Ladika'840. Since the end result product meets the recited structure, the manner of making is not limiting.

Regarding claim 23, Bodicky further teaches that the chosen tubing is suitable for high-pressure injections at a pressure of at least about 1200 psi (column 3, lines 17-20, since 1000 psi is "about" 1200 psi).

3. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Ladika and Bodicky as applied to claims 1, 2, 6, 8-11, and 23 above, and further in view of Miller (US Patent 5683640).

Regarding Claim 3, Martin in view of Ladika and Bodicky discloses all the elements of the current invention, as applied to Claim 1 above, except for the dual lumen portion having a diameter of greater than 6 French and the single lumen portion having a diameter less than or equal to 6 French. Miller discloses a dual-lumen catheter

comprising a dual lumen portion with a diameter of greater than 6 French and a single lumen portion with a diameter of less than or equal to 6 French (column 4, lines 3-8), so that the device will properly fit within the vessels of a patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the catheter of Martin in view of Ladika and Bodicky with the dimensions of Miller, so that the device will properly fit within the vessels of a patient.

Regarding Claim 4, Martin in view of Ladika and Bodicky discloses all the elements of the current invention, as applied to Claim 3 above, except for the dual lumen portion having a diameter of between about seven French and about 8 French. Miller further discloses that the dual lumen portion of the catheter has a diameter between about 7 and about 8 French (column 4, lines 3-5), so that the device properly fits within a patient's vessels. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the catheter of Martin in view of Ladika and Bodicky with the dual lumen portion dimensions of Miller, so that the device properly fits within a patient's vessels.

Regarding Claim 5, Martin in view of Ladika and Bodicky discloses all the elements of the current invention, as applied to Claim 3 above, except for the single lumen portion having a diameter of about 5 French. Miller further discloses that the single-lumen portion of the catheter has a diameter of about 5 French (column 4, lines 6-7), so that it may easily maneuver within a patient's vessels. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have

made the catheter of Martin in view of Ladika and Bodicky with the single lumen portion dimensions of Miller, so that the device may easily maneuver within a patient's vessels.

4. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Ladika and Bodicky, as applied to claims 1, 2, 6, 8-11, and 23 above, and further in view of Duffy (US Patent 6048332).

Martin in view of Ladika and Bodicky discloses all the elements of the current invention, as applied to Claim 1 above, except for the outer lumen side holes being distributed spirally over about 4 centimeters of the lumen. Duffy teaches a catheter comprising an outer lumen (element 20) with spirally distributed holes (element 32) (see Figures 4 and 5b), wherein the length of the portion with the holes is about 4 centimeters (column 8, lines 42-45), in order to properly interact with the patient's fluids. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the catheter of Martin in view of Ladika and Bodicky with the spirally distributed holes of Duffy, in order for the device to properly interact with the patient's fluids.

Response to Arguments

5. Applicant's arguments filed 14 February 2007 have been fully considered but they are not persuasive.

Applicant argues that, because Bodicky teaches that braided catheter tubing is useful for high pressure injection, no other material would be suitable, and feels that it

teaches away from the use of any other material, such as those used by Martin or Ladika. The examiner disagrees because Bodicky has not excluded any other material; Bodicky merely provides support for choosing to use braided catheter tubing. As for Applicant's argument that there is no reason to use such tubing in Martin or Ladika, firstly, not motivation must be provided to use such tubing in Ladika, since Bodicky is being used to modify the system of only Martin. Further, it would be reasonable to consider using braided catheter tubing in Martin, since its use is, as shown by Bodicky, well known in the cardiac catheter art, and it would merely be the substitution of one catheter component for another.

Regarding the argument that there is no suggestion to use different materials for the inner wall than an outer wall of a dual lumen catheter, Applicant has not claimed that the inner lumen is of a different material than the outer lumen. The claimed invention merely has an inner lumen comprising braided extrusion reinforcement, with no limitations as to the material(s) comprising the outer lumen. As such, there is no reason why the braided extrusion tubing of Bodicky may not be used to form the catheter system of Martin, using braided extrusion tubing to form both the inner and outer lumens.

The rejections stand as FINAL.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ket